

Docket No.
357089/150
SBP/CEC

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Wallis Waremu Toataua Farraday Art Unit No.: 3772
Application No.: 10/789,228 Confirmation No.: 7967
Filed: February 26, 2004 Examiner: Kari Kristen Patrick
For: **POST-OPERATIVE DRESSING FOR BELOW KNEE AMPUTEE**

DECLARATION OF WALLIS FARRADAY UNDER 37 C.F.R. 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Wallis Wiremu Toataua Farraday, declare as follows:

1. I am the inventor of the inventions described and claimed in the subject Application and am an employee of the assignee, Hanger Orthopedic Group, Inc.
2. I have a Prosthetics equivalent degree from the Central Institute of Technology, New Zealand, as recognized by World Education Services, New York and have over 32 years of experience in orthopedic devices, specifically lower extremity Prosthetics and management systems such as those disclosed, described and claimed in the subject Application. My initial Prosthetic Rigid Post Operative Dressing experience began at the University of Toronto, Health Sciences Centre, Sunnybrook centre for Independent living. Based on my education and experience, I am at least one of ordinary skill in the art to which the Application pertains.
3. I am familiar with the Application and the amendments thereto, the claims of the Application as they presently stand, the Office Action dated December 2, 2008, and the

references cited therein. This Declaration is submitted in support of, and is intended to form part of, the response to the December 2, 2008 Office Action.

4. I have read the Application as filed and it would be clear to one of ordinary skill in the art that the Application is directed towards a non-weight bearing post-operative rigid protective dressing for a limb, and that the post-operative dressing is designed to be applied in the operating room or recovery rooms immediate post surgery or within 10 days of amputation of the limb. Support for such an understanding is evidenced from at least the following.

5. One of ordinary skill in the art, upon reading the Application, would understand that the device disclosed in the Application is directed towards “an immediate post-operative limb protection dressing.” See paragraphs 2, 10, 25 and 27 by way of example. In addition, the Application describes how the “rehabilitation team” applies the dressing after amputation (see paragraph 009, by way of example), and that the dressing is designed to “enhance residual limb definition and accelerate rehabilitation time.” See paragraph 11 by way of example. The Application also describes how the dressing is designed to reduce and or prevent flexion contractures, protect the limb from trauma, and negate external influences on healing, and to provide for easy quick inspection of the limb during initial postoperative care (see paragraphs 13, 14 and 16 by way of example).

6. Based on at least the foregoing, one of ordinary skill upon reading the Application would understand that the post-operative dressing disclosed and described in the Application is designed to be applied within 10 days of amputation of the limb and not intended to for ambulation or to promote ambulation.

7. Based on the materials used in connection with the dressing and the manner and orientation in which they are formed, together with the fact that the dressing is intended to be

applied within 10 days of amputation, one of ordinary skill in the art would also understand that the post-operative dressing disclosed and described in the Application is a non-weight bearing device and is not intended to walk on or with. This is further supported by the fact that the Application discloses that the dressing is particularly suited for amputees that "have no potential for ambulating" as disclosed in paragraph 34 of the Application.

8. The device disclosed in the Application uses a non fabric backed thermo plastic liner which assists in controlling edema. As described at paragraph 27, the liner is preferably transparent so that the limb can be inspected through the liner without needing to remove the liner from the limb.

9. I have also reviewed U.S. Patent No. 5,571,208 to Caspers ("Caspers"), U.S. Patent No. 5,830,237 to Kania ("Kania"), U.S. Patent No. 6,368,357 to Schon et al. ("Schon") and Application Publication No. 2003/0114783 to Vanden ("Vanden"). I have also reviewed the manner in which these references have been applied in the December 2, 2008 Office Action.

10. The references do not teach or suggest to one of ordinary skill in the art "providing a non-weight bearing post-operative protection to a limb within ten days from amputation of a limb" as recited in independent claims 12 and 16 of the Application. More over they keep and promote weight bearing and ambulation potential.

11. Caspers, Kania, Schon and Vanden are each directed towards weight bearing devices. Casper describes the liner and sleeve for "donning over a residual limb and fitting within the socket of an artificial limb, clearly indicating one of an ordinary skill that the device is intended to promote and enhance ambulation ." (Abstract; Col. 3, lines 54-55). Casper continues to describe the drawbacks associated with artificial limbs and their socket liners available, and further describes its liner as being used for artificial limbs. One of ordinary skill in the art would

understand that an artificial limb is a weight bearing device intended for ambulation. In fact, Casper explicitly states that its device is directed toward a “weight bearing” device. (See Col. 3, line 46; col. 6, line 62; col. 7, lines 1-5; col. 9, lines 9). Accordingly, Casper does not teach or suggest to one of ordinary skill in the art “providing a non-weight bearing post-operative protection” as claimed in the Application.

12. Kania is directed to a fabric-lined (i.e., non-transparent) gel for use with a weight bearing device, and more specifically for providing cushioning and one of an ordinary skill would be lead to anticipate comfort between a limb and a prosthetic device. Kania describes the use of gels for minimizing the discomfort of “a prosthetic device, such as an artificial arm or leg.” (Col. 1, lines 18-20) and to provide cushioning “between the residuum and a prosthetic device socket.” (Col. 3, lines 56-59; col. 4, lines 1-2; col. 6, line 67 to col. 7, line 1). Accordingly, one of ordinary skill in the art would understand that Kania is directed towards a weight bearing device, intended for ambulation and Kania does not teach or suggest to one of ordinary skill in the art a “non-weight bearing” device as claimed in the Application.

13. Schon is also directed to a weight bearing device intended for ambulation. Schon provides that its system “could also be used with an attachable pylon and foot to promote symmetrical body image and the psychological well-being of the amputee, and will also permit early partial weight bearing, again leading one of an ordinary skill to expect ambulation capability.” (Col. 2, lines 40-43). Schon also states “[t]he use of the therapeutic device 20 of the present invention in conjunction with a pylon 60 and foot 62 immediately after surgery helps the amputee develop balance and a tolerance to weight bearing and prevents contractures and loss of muscle strength.” (Col. 6, lines 54-59). Accordingly, one of ordinary skill in the art would understand that Schon is directed towards a weight bearing, ambulating device, and Schon does

not teach or suggest a “non-weight bearing non ambulating” device as claimed in the Application.

14. Vanden is also directed to a weight bearing device. Vanden is directed to an orthopedic device having a clam shell having an implement attached thereto. One of ordinary skill in the art would understand that such a device is a weight bearing device. Furthermore, Vanden is directed to addressing hand and wrist dysfunctions, and not a “recently amputated residual limb” of the lower extremity as described and claimed in the Application. One of ordinary skill in the art would understand that a non-weight bearing device lacking an implement would defeat the objectives of Vanden and render it unsuitable for its purpose. Thus it would not have been obvious (or desirable) to one of ordinary skill in the art to modify Vanden to provide a non-weight bearing device.

15. Casper, Kania, Schon and Vanden do not teach or suggest to one of ordinary skill in the art that the devices disclosed therein are to be applied “within ten days from amputation” as recited in claims 12 and 16 of the Application.

16. Casper, Kania and Vanden are not directed to devices provided within ten days from amputation. In fact, Casper, Kania and Vanden are not directed to “recently amputated residual limb” or to treating a residual limb within ten days of amputation. One of ordinary skill in the art would understand that the weight bearing devices disclosed in Casper, Kania and Vanden would not be provided on a recently amputated residual limb. To do so would likely apply too much pressure on the residual limb and would not compress and contain the limb. One of ordinary skill in the art would understand that the devices described Casper, Kania and Vanden would not be suitable for a recently amputated residual limb within ten days from amputation.

17. I hereby declare that all statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated: June 15th, 2009

Wallis Waremu Toataua Farraday
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